



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

FILE COPY

May 9, 2000

Loretta A. Mooney
Prizm Medical, Inc.
3400 Corporate Way, Suite 1
Duluth, GA 30096

Dear Ms. Mooney:

Your petition requesting the Food and Drug Administration to allow a variance to extend the effective date Performance standard for electrode lead wire & patient cables from May 9, 2000 to August 9, 2000, was received by in this office on 05/09/00. It was assigned docket number 00P-1290/CP1 and it was filed on 05/09/00. Please refer to this docket number in future correspondence on this subject with the Agency.

Please note that the acceptance of the petition for filing is a procedural matter in that it in no way reflects an agency decision on the substantive merits of the petition.

Sincerely,

A handwritten signature in cursive script, reading "Helen K. Harris", is written over the typed name.

Helen K. Harris
Dockets Management Branch

ACK1